

DEPARTMENT OF HEALTH AND HUMAN SERVICES

WARNING LETTER

MAR - 4 1998

Certified Mail
Return Receipt Requested

Ref. No.: 02-98-4011-340

Beppino C. Giovanella, Ph.D.
Laboratory Director
Stehlin Foundation for Cancer Research
1918 Chenevert
Houston, TX 77003

Dear Dr. Giovanella:

Your facility was inspected between November 17 and November 21, 1997, and between January 12 and January 21, 1998, by investigators from FDA's Houston District Office to review your firm's activities related to your conduct of nonclinical laboratory studies. These inspections are a part of FDA's Bioresearch Monitoring program which is designed, in part, to validate the quality and integrity of nonclinical safety data. These inspections covered studies that your firm conducted in support of the following Investigational New Drug Applications:

[REDACTED]

Following our evaluation of reports of these inspections and your subsequent correspondence with FDA's Dallas District Office, we conclude that your firm has violated FDA regulations in that 1) you did not have study protocols, relevant standard operating procedures (SOPs), a quality assurance unit, and final reports, 2) you did not have records of test article preparation and characterization, dosing information, and histopathological evaluations, 3) you did not notify a contract laboratory of the need to conduct studies in compliance with Good Laboratory Practice (GLP) regulations in Title 21, Code of Federal Regulations, Part 58, and 4) you falsely stated, in regard to [REDACTED] that "Every experiment was conducted in compliance with the GLPs." Because of the lack of complete records, our inspection teams have been unable to reconstruct the events of your studies.

Specific examples of the violations are cited in the two Inspectional Observations Forms FDA 483 issued to you.

WARNING LETTER - STEHLIN FOUNDATION FOR CANCER RESEARCH

Because of the nature and severity of the deviations, we are recommending to the appropriate FDA new drug evaluation division that any safety studies conducted in support of [REDACTED], [REDACTED], and [REDACTED] should not be used to support those applications.

The above description of our findings is not intended to be an all-inclusive list of violations and deficiencies at your facility. This letter is notification that the GLP deficiencies observed during this inspection must be corrected before new nonclinical safety studies intended for submission to FDA are planned or begun. Prior to initiation of any further new studies, you should request from the FDA Dallas District Office that your laboratory be reinspected. Further, any studies conducted prior to corrections being verified should be amended to include a statement that the study was not conducted in compliance with the GLP regulations, and should include a brief description of the reasons for noncompliance.

Please notify this office in writing within fifteen (15) working days of receipt of this letter and indicate your intentions to immediately correct the GLP violations, and/or assure the Agency that you will conduct no further studies which are subject to the GLP regulations until corrections are made and verified.

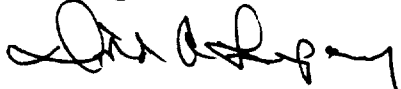
We consider this a serious matter and urge you to respond. Failure to respond may result in further Agency action.

If you have any questions concerning these matters, or the Good Laboratory Practice regulations, please contact:

C.T. Viswanathan, Ph.D.
Associate Director
Division of Scientific Investigations
Office of Compliance
Center for Drug Evaluation and Research
7520 Standish Place, Room 151
Rockville, MD 20855
Telephone: (301) 594-5460

WARNING LETTER - STEHLIN FOUNDATION FOR CANCER RESEARCH

Sincerely,

A handwritten signature in black ink, appearing to read 'David A. Lepay', written in a cursive style.

David A. Lepay, M.D., Ph.D.
Director
Division of Scientific Investigations
Office of Compliance
Center for Drug Evaluation and Research

Enclosure: 2 FDA 483s

cc:

John S. Stehlin, Jr., M.D.
Stehlin Foundation for Cancer Research